

¹ Pursuant to Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims (Appendix B to the Rules of the United States Court of Federal Claims), this opinion was initially filed under seal on June 19, 2019. Pursuant to ¶ 4 of the ordering language, the parties were to propose redactions of the information contained therein on or before July 3, 2019. No proposed redactions were submitted to the court.

Respondent filed its response brief on March 22, 2019. See ECF No. 34. Petitioner's motion is fully briefed and ripe for decision.

The special master denied petitioner compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (the Vaccine Act). As explained below, the special master's entitlement decision survives this court's review. Accordingly, petitioner's motion for review is **DENIED**.

I. Background

Petitioner filed this case seeking compensation for an injury suffered by H.B., allegedly as the result of receiving the influenza vaccine, FluMist, at the age of eight. See ECF No. 1. In reaching his decision, the special master identified the following relevant facts.²

H.B. was born on May 16, 2006. See ECF No. 30 at 2. During his first year of life, his development appeared normal, though he was treated for several illnesses, including Lyme disease. See id. H.B. was first diagnosed with a delay in speech development by his pediatrician at his eighteen-month well-visit. See id. Similar notes were made at his two-, three-, and four-year well-visits. See id. In addition to the speech delays, his doctor noted sensory issues at H.B.'s four-year well-visit. See id. At his five-year well-visit, H.B.'s doctor assessed him with a "listening comprehension disability," in addition to the previously noted concerns. Id. At preschool, H.B. exhibited language skills in the "low range." Id. And his six-, seven-, and eight-year well-visits noted that H.B. was participating in occupational and speech therapy to address these concerns. See id.

On October 22, 2014, H.B. received the FluMist vaccine, and experienced no immediate adverse reaction. See id. On December 14, 2014, H.B. was seen by a neurologist for an "evaluation of his inattention and learning disabilities." Id. The neurologist appointment was H.B.'s first medical appointment following administration of the vaccine. Id. The neurologist diagnosed H.B. with Attention-Deficit/Hyperactivity Disorder (ADHD), and made no mention of the vaccine in his notes. See id. On January 28, 2015, H.B. visited his pediatrician "with complaints of speech, recall, and slight motor regression," but the doctor noted "no obvious signs of increasing . . . regression." Id. The doctor "assessed [H.B.] with '[l]earning difficulties' and possible underlying development delay." Id.

Neurological examinations on February 18 and February 21, 2015, noted a history of "[r]egression in skills" beginning in November to December 2014, and noted reports

² For clarity of the narrative, the court has omitted the extensive citations to the record included in the special master's decision.

of “processing issues and academic struggles from an early age.” Id. The fact that H.B. received the FluMist vaccine was recorded, but the notes from his neurological evaluation specifically stated that he did not show signs of any adverse reaction to the vaccine. See id. at 2-3. “The examination revealed below average processing/memory skills and ‘severe’ fine motor/visual motor deficits, along with below average gross motor and language skills.” Id. at 3. The doctor recommended further consideration of “progressive neurodegenerative disorder, neuro-metabolic disorder, mitochondrial disorder/abnormalities, and storage disorder.” Id. H.B. had a magnetic resonance imaging (MRI) test on March 3, 2015, the results of which were “normal.” Id.

H.B. was evaluated by both a neurologist and a rheumatologist at Goryeb Children’s Hospital in March 2015. The examinations noted H.B.’s past developmental delays and regression in the preceding year. Id. The rheumatologist cited “H.B.’s receipt of the FluMist vaccine . . . , but [the doctor’s] notes asserted (contrary to the medical history) the vaccination ‘preceded many of his symptoms according to his mother.’” Id.

On April 1, 2015, H.B. was evaluated by his pediatrician for “worsening ADHD symptoms.” Id. During that visit, his father stated that H.B.’s symptoms “began soon after” he received the FluMist vaccine. Id. The next day, an infectious disease specialist evaluated H.B., and considered a diagnosis of Sydenham’s chorea or PANDAS, but did not make a final decision as to either. See id. In June, H.B.’s doctors discussed diagnoses for a movement disorder, post-acute immune syndrome, and active Lyme disease. See id. Also in June 2015, H.B. was hospitalized for psychosis, and the hospital notes suggested a concern that he is autistic. The hospital administered a second MRI, which again was “normal.” Id.

In April 2015, H.B. was evaluated by another neurologist, Dr. Rosario Trifiletti.³ In an exam note dated April 22, 2015, Dr. Trifiletti referenced H.B.’s FluMist vaccine, but did not discuss the vaccine’s relationship to H.B.’s symptoms. See id. During following visits in November 2015, December 2015, and May 2017, Dr. Trifiletti recorded concerns about autoimmune encephalopathy, anxiety, obsessive-compulsive disorder behaviors, and autism, but did not connect those conditions with the FluMist vaccine. See id. at 3-4.

Finally, on October 17, 2016, H.B. attended an additional neurology consult at the Children’s Hospital of Pennsylvania. See id. at 4. The health history from that appointment listed the following: “regression (with onset in 2014), PANDAS, ADHD, Lyme disease, and Sydenham’s chorea.” Id. “The differential diagnosis included autoimmune encephalitis and genetic/metabolic disorder,” but testing was negative for

³ Petitioner, respondent, and the special master refer to Dr. Trifiletti, but the doctor’s letterhead and signature spell his name Trifiletti. See, e.g., ECF No. 27-3 at 1.

autoimmune encephalitis. Id. In November 2016, H.B. had a third MRI, which was “unremarkable.” Id.

In his motion for review of the special master’s decision, petitioner does not object to the special master’s recitation of the facts and supporting medical records. Petitioner’s short statement of the case includes only the following facts related to H.B.’s medical condition:

H.B. is a twelve year-old boy born in Morristown, New Jersey as one of a set of identical twins. For the first eight years of his life, H.B. was a healthy child. Just like his brother, H.B. had a slight speech delay, but no other significant health issues. On October 22, 2014, H.B.’s life changed. After receiving the Flumist vaccination, H.B. began to regress in his speech and recall ability in a matter of weeks. After many failed attempts to treat H.B.’s condition by many different specialists, Dr. Rosario [Trifiletti] diagnosed him with autoimmune encephalopathy and began IVIg treatment. Dr. [Trifiletti] believed H.B.’s condition was related to the administration of the Flumist vaccine.

ECF No. 31-1 at 2 (citations omitted). Petitioner’s assertion that Dr. Trifiletti believed H.B.’s condition was related to the vaccine he received is apparently based on the following statement in a referral letter from Dr. Trifiletti to the Psychology Program at Children’s Specialized Hospital: “[H.B.] has been treated for autoimmune encephalopathy (G93.40), which seemed to occur with sudden onset following an influenza vaccine in early 2015.” ECF No. 27-3 at 1; see also ECF No. 31-1 at 9.

On July 31, 2018, respondent filed its report pursuant to Rule 4(c) of the Rules of the United States Court of Federal Claims, Appendix B (Vaccine Rules). See ECF No. 25. Therein, respondent argued that petitioner was not entitled to recover for H.B.’s injury because “on the existing record . . . petitioner has failed to establish by preponderant evidence that H.B.’s conditions were caused or significantly aggravated by the FluMist vaccination.” Id. at 12. On August 23, 2018, the special master convened a status conference to discuss deficiencies in petitioner’s medical evidence. See ECF No. 26 (status conference order). Following the conference, the special master directed petitioner to “file a brief showing cause why his claim should not be dismissed due to a lack of reasonable basis.” Id. at 2. After reviewing both petitioner’s brief, ECF No. 27, and respondent’s response, ECF No. 29, the special master dismissed the petition, see ECF No. 30.

II. Legal Standards

This court has jurisdiction to review the decision of a special master in a Vaccine Act case. 42 U.S.C. § 300aa-12(e)(2). “Under the Vaccine Act, the Court of Federal

Claims reviews the decision of the special master to determine if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]’” de Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008) (quoting 42 U.S.C. § 300aa-12(e)(2)(B) and citing Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)).

This court uses three distinct standards of review in Vaccine Act cases, depending upon which aspect of a special master’s judgment is under scrutiny.

These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the “not in accordance with law” standard; and discretionary rulings under the abuse of discretion standard.

Munn v. Sec’y of Dep’t of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

Petitioner bears the burden of proving, by a preponderance of the evidence, that “the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278. “Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” Broekelschen v. Sec’y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)).

III. Analysis

Petitioner objects to the special master’s decision for three reasons. First, petitioner alleges that the special master erred by applying the “reasonable basis standard” in considering whether petitioner’s medical evidence was sufficient to support his claim. See ECF No. 31-1 at 3-5. Second, petitioner claims that the special master erred in dismissing the case before allowing petitioner to submit an expert report. See id. at 6-7. And finally, petitioner argues that the special master placed too much emphasis on the medical records that pre-dated the vaccination. See id. at 7-9. The court will address each argument in turn.

A. The Special Master Did Not Err in Evaluating the Basis for Petitioner's Claim

Petitioner articulates his first objection as follows: “The special master’s decision erroneously conflates the standards of ‘reasonable basis,’ which, per statute, only has application in the context of a petition for fees and costs, and that of causation, which requires a showing of preponderant evidence.” Id. at 3 (citing 42 U.S.C. § 300aa-15(e)(1)). According to petitioner, by discussing causation in terms of establishing a reasonable basis, rather than a preponderance of the evidence, “the special master incorrectly held Petitioner to a higher standard of proof than is required.” Id. at 4. Because the applicable standard of proof is a legal question, this court reviews this aspect of the special master’s decision de novo. See Hammitt v. Sec’y of Health & Human Servs., 98 Fed. Cl. 719, 725 (2011) (citing Broekelschen, 618 F.3d at 1345).

The problem with petitioner’s argument is two-fold. First, the court disagrees with petitioner’s assertion that the special master applied the reasonable basis standard in reaching his ultimate conclusion that petitioner’s case should not proceed. At the outset of his analysis, the special master stated that because petitioner did not claim an injury reflected by the Vaccine Injury Table, petitioner must “establish entitlement via a causation-in-fact, non-Table claim—meaning he must meet the test for such a claim set forth by the Federal Circuit in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005).” ECF No. 30 at 6. As noted above, the Althen standard specifically requires that a petitioner prove his case by a preponderance of the evidence. See Althen, 418 F.3d at 1278. As such, the court reads the special master’s citation to Althen as an invocation of the preponderance standard.

The special master did use the phrase “reasonable basis” twice in his analysis of the foundation for petitioner’s claim. See ECF No. 30 at 8 (“Furthermore, the case law cited by Petitioner in [an] attempt[] to bolster the claim is not supportive of a finding of reasonable basis to proceed.”); and (“Given the above, the claim as alleged lacks reasonable basis, and is appropriately dismissed.”). But the special master framed his central conclusion, as follows:

Petitioner has had several chances to offer evidence into the record that would support his claim. The record, however, does not contain sufficient persuasive evidence establishing that H.B.’s developmental problems were initiated by the FluMist vaccine via the theory proffered herein. Thus, after careful review of the medical records and Petitioner’s filings, I concluded that Petitioner will not be able to establish preponderant evidence in favor of his claim, therefore the matter should not proceed any further.

ECF No. 30 at 6 (citations omitted). This formulation of the special master's ultimate finding makes clear that he was looking to the preponderance standard as the measure for whether petitioner met his burden in this case.

Nonetheless, even if the special master conflated the reasonable basis and preponderance standards in the course of his analysis, the court finds such an error to be a harmless one. The reasonable basis standard, which petitioner correctly identifies as the standard required when considering an award of attorneys' fees, is—contrary to petitioner's assertions—less exacting than the preponderance of the evidence standard and thus, is easier to satisfy. The analysis in Austin v. Secretary of the Department of Health and Human Services, No. 10-362V, 2013 WL 659574 (Fed. Cl. Jan. 31, 2013), is instructive on this point. Therein, the special master explains:

For purposes of awarding fees and costs, the Vaccine Act creates three classes of litigants, two explicitly, and one by implication. The first class is comprised of those petitioners who establish vaccine causation of an injury. They are entitled to the award of reasonable attorneys' fees and costs as part of the compensation for their claim. § 15(e)(1)(A) and (B). Those who do not prevail on the merits of their petition fall into one of the other two classes.

The second class is comprised of those litigants who can demonstrate that their unsuccessful claim was brought in good faith and upon a reasonable basis. They may, in the discretion of the special master, be awarded reasonable fees and costs. § 15(e)(1)(A) and (B)

The third class is the one created by implication, for if only the losing litigants who establish reasonable basis and good faith are eligible to receive fees and costs, it follows that those who fail those tests may not be awarded fees and costs.

Id. at *7. This delineation of the paths on which a vaccine case may travel makes clear that a petitioner can establish a reasonable basis for his claim without proving causation by a preponderance of the evidence, but a petitioner can not prove causation without also establishing a reasonable basis for the claim. Put another way, under the structure of the Vaccine Act, there is no category of petitioner who fails to show a reasonable basis for his claim, but successfully proves causation by a preponderance of the evidence.

Assuming, for the sake of evaluating petitioner's argument, that the special master dismissed petitioner's case for failing to meet the reasonable basis standard, the logical implication of such a finding is that petitioner also would be unable to carry the heavier preponderance burden. As such, petitioner's claim was properly dismissed, and any error was harmless in the analysis of petitioner's claim.

The court notes that despite its decision to sustain the special master's decision as to the petitioner's first objection, petitioner's confusion regarding the standard applied was not altogether unreasonable. The court encourages continued efforts at achieving precision as the special masters work to fairly and efficiently administer justice through the Vaccine Program. Such precision allows not only for effective review, but also for effective communication of the special master's decision to the petitioner.

B. The Special Master Did Not Err by Dismissing the Case before Allowing Petitioner to File an Expert Report

According to petitioner, the special master erred in dismissing the petition before affording petitioner the opportunity to submit an expert report. Specifically, petitioner alleges the special master acted improperly because: (1) once counsel was retained, he consulted with an expert, Dr. Lawrence Steinman, who provided "assurances . . . of the feasibility of the claim," ECF No. 31-1 at 6; (2) special masters have previously found that "a reasonable basis can still exist where an expert interprets ambiguous evidence to reach a result that differs from the court's interpretation," id.; (3) the special master knew of Dr. Steinman's involvement with the case, see id.; and (4) the cases cited by the special master were cases in which expert reports were considered, see id. at 7.

The special master explained his decision to dismiss the case without allowing petitioner to file an expert report, as follows:

Ultimately, the medical record itself is fatal to Petitioner's claim. The record contains unexplained and unrebutted facts that suggest either H.B.'s injuries predated vaccination, or that they are attributable to an entirely different illness (given the multiple differential explanations noted in his overall health course). But most importantly, the record contains no evidence of an encephalopathic injury close-in time to H.B.'s receipt of the FluMist vaccine, and the treater statements offered over one year post-vaccination are not persuasive given the extensive contemporaneous record. An expert opinion would not aid Petitioner in light of this absence.

ECF No. 30 at 8.

When the special master excludes evidence or otherwise limits the record upon which he relies, such decisions are reviewed for an abuse of discretion. See Munn, 970 F.2d at 870. A special master abuses his discretion when: "(1) the [special master's] decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision is based on an erroneous conclusion of the law; (3) the [special master's] findings are clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision." Stillwell v. Sec'y of Health & Human Servs., 118 Fed. Cl. 47, 55 (2014) (quoting Hendler v. United States, 952 F.2d 1364, 1380 (Fed. Cir. 1991)).

Determinations subject to review for abuse of discretion must be sustained unless “manifestly erroneous.” Piscopo v. Sec’y of Health & Human Servs., 66 Fed. Cl. 49, 53 (2005) (citations omitted); see also Milmark Servs., Inc. v. United States, 731 F.2d 855, 860 (Fed. Cir. 1984) (holding that decisions within the trial court’s discretion are to be sustained unless “manifestly erroneous”) (citation omitted).

Contrary to petitioner’s suggestion, the special master’s decision to dismiss the petition before hearing expert testimony was not an abuse of his discretion. It was the special master’s considered opinion that the deficiencies in the medical record could not be overcome by any findings an expert report might offer. The special master found not—as petitioner suggests—that the record contained ambiguous evidence, but rather that it contained “no evidence of an encephalopathic injury close-in-time to H.B.’s receipt of the FluMist vaccine.” ECF No. 30 at 8. Because the special master based his decision on an extensive review of the medical records at issue here, his decision was not arbitrary. Nor was the decision clearly erroneous—as the record evidence recited by the special master, and reproduced at length above, supports his conclusion. The fact that the special master knew that Dr. Steinman was involved with the case is simply immaterial to the determination of whether his testimony would be of value in the proceedings.

C. The Special Master Did Not Err in Considering H.B.’s Pre-Vaccination Medical Records

In his final objection, petitioner argues that the special master “incorrectly gives greater weight to the scant evidence in the record of H.B.’s pre-vaccination condition than the wealth of evidence demonstrating H.B.’s severe regression post-vaccination.” ECF No. 31-1 at 7. Petitioner compliments the special master’s recitation of H.B.’s medical history, but takes issue with his treatment of those records. “The special master’s decision does well to review the extensive record submitted by Petitioner, however, the weight given to H.B.’s pre-vaccination development and possible ASD diagnosis is arbitrary in light of the substantial post-vaccination evidence of an autoimmune encephalopathy with severe regression.” Id. at 9.

Such findings of fact are properly reviewed by the court under the arbitrary and capricious standard, which is “well understood to be the most deferential possible” review. Munn, 970 F.2d at 870. “Accordingly, it is not the role of this court to ‘reweigh the factual evidence,’ ‘assess whether the special master correctly evaluated the evidence,’ or ‘examine the probative value of the evidence or the credibility of the witnesses.’” Stillwell, 118 Fed. Cl. at 55 (quoting Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000)). “If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” Hines v. Sec’y of Dep’t of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991).

Here, the special master appropriately considered all of H.B.'s medical records. This is, in fact, his charge. See 42 U.S.C. § 300aa-13(a)(1) (stating, in part, that the special master may not find that a petitioner is entitled to compensation "based on the claims of the petitioner alone, unsubstantiated by medical records or medical opinion"); see also 42 U.S.C. § 300aa-13(b)(1)(A) ("In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider . . . any diagnosis, conclusion, [or] medical judgment . . . which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death.").

Moreover, in order to prove his case, petitioner must demonstrate that the vaccine brought about H.B.'s injury by providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. In order to effectively evaluate any part of this test, the special master would necessarily need to consider H.B.'s physical and mental condition prior to receiving the FluMist vaccine. Without such a foundational understanding of H.B.'s health, the special master would not be able to evaluate whether any changes occurred after H.B. received the vaccine.

The special master's analysis of H.B.'s medical records was detailed and thoughtful. He recited the facts, explained the parties' arguments, discussed applicable case law, and engaged in a thorough discussion of H.B.'s medical condition. While the special master did note that the post-vaccination records "must be weighed against the substantial medical evidence strongly suggesting that H.B. had experienced developmental problems long before the vaccination," ECF No. 30 at 7, he devoted a greater portion of his analysis to discussing deficiencies in the post-vaccination records, id. at 7-8. The court understands that petitioner disagrees with the special master's analysis, but in such circumstances, it is not the purview of the court to "reweigh the factual evidence," or to substitute its judgment for that of the special master. Stillwell, 118 Fed. Cl. at 55 (citation omitted). Because the special master considered the relevant evidence, drew plausible inferences, and articulated a rational basis for his decision, the court concludes that the weight the special master assigned to H.B.'s pre-vaccination records was not in error.

IV. Conclusion

For the above-stated reasons, the court sustains the special master's decision to dismiss petitioner's case. Accordingly, it is hereby **ORDERED** that:

- (1) Petitioner's motion for review, ECF No. 31, is **DENIED**;

- (2) The decision of the special master, filed January 25, 2019, ECF No. 30, is **SUSTAINED**;
- (3) The clerk's office is directed to **ENTER** final judgment in accordance with the special master's January 25, 2019 decision, ECF No. 30; and
- (4) The parties shall separately **FILE** any **proposed redactions** to this opinion, with the text to be redacted clearly blacked out, on or before **July 3, 2019**.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
PATRICIA E. CAMPBELL-SMITH
Judge